# PSJ3 Exhibit 456A

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

#### **EXECUTIVE COMMITTEE MEETING**

The Lodge at Pebble Beach Pebble Beach, CA

February 16, 2012

CONFIDENTIAL HDA\_MDL\_000156141

# Minutes of the HDMA Executive Committee Meeting

#### The Lodge at Pebble Beach Pebble Beach, CA

#### February 16, 2012

#### **ATTENDEES**

#### **HDMA Executive Committee Members Present:**

David Moody (Chair) CEO, Mutual Wholesale Drug Company

David Neu (Vice Chairman) President, AmerisourceBergen Drug Corporation

(by teleconference)

Ken Couch
John M. Gray
President, Smith Drug Company
President and CEO, HDMA
Ted Scherr
President and CEO, Dakota Drug
Dale Smith
Chairman and CEO, HD Smith

#### **HDMA Executive Committee Members Absent:**

Paul Julian Executive Vice President and Group President, McKesson Corp.

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

#### **HDMA and CHSCR Staff:**

Ann W. Bittman Executive Vice President and COO

Perry Fri Senior Vice President, Industry Relations, Membership and

Education

Elizabeth Gallenagh, Esq. Vice President, Government Affairs and General Counsel

(by teleconference)

Patrick Kelly Senior Vice President, Government Affairs

Karen Ribler Executive Vice President & COO, Center for Healthcare

Supply Chain Research (CHSCR)

#### **Outside Legal Counsel:**

Richard L. Frank, Esq. Olsson Frank Weeda Matz PC (OFW Law)

#### Guests:

William Hale The Hale Group George W. Koch, Esq. K&L Gates

#### **PROCEEDINGS**

#### I. <u>WELCOME AND INTRODUCTION.</u>

A. Mr. Dave Moody (HDMA Chairman) called the meeting to order at 7:00 a.m. and welcomed the Executive Committee to Pebble Beach, California. Mr. Dave Neu (AmerisourceBergen Drug Corporation) joined the meeting by teleconference.

#### B. Approval of Prior Meeting Minutes (Executive Committee Book, Pages 5-10).

Richard L. Frank (OFW Law), HDMA Outside Counsel, drew the Executive Committee's attention to minutes of the October 16, 2011 Executive Committee meeting.

Action: On motion duly made and seconded, the minutes of the October 16, 2011 Executive Committee meeting were approved.

#### C. Antitrust Policy Review (Executive Committee Book, Page 3).

Mr. Frank drew the Executive Committee's attention to the HDMA Antitrust Policy. He reminded the Executive Committee of HDMA's unqualified policy of strict compliance with the antitrust laws and noted that the agenda and background materials had been reviewed and approved by counsel in advance. Mr. Frank advised that meeting proceedings would be closely monitored and interrupted if and when topics or discussions created even the appearance of antitrust noncompliance.

#### D. <u>Legal Issues Report</u>.

Mr. Frank presented a short legal issues update.

- RxUSA v. HHS/FDA FDA consideration of proposed revisions to PDMA regulations to remove those provisions which have been stayed by the U.S. federal court is pending. HDMA filed comments in support of the FDA proposal.
- FDA Grand Jury in Puerto Rico distributor investigation. Responsive documents have been produced. The FDA OCI Investigator and Assistant U.S. Attorney have requested an interview with HDMA staff for factual background. HDMA is not a target. HDMA is awaiting proposed dates.
- Par Pharmaceuticals/AWP Litigation Nothing new to report since the last meeting.
- Qui Tam Litigation Defendants filed a motion to dismiss. Plaintiff Streck filed his opposition on February 10, 2012; defendants' reply is due on February 24, 2012.

- Cardinal Health v. Holder (DEA); CVS v. Holder (DEA) these actions, challenging DEA's order shutting down Cardinal and CVS facilities in Florida were briefly discussed by Messrs. Frank and Kelly. Federal district courts in Washington, D.C. and Florida have issued temporary restraining orders against DEA. This matter will be further discussed later during the meeting.
- Project Paperless President Gray updated the Executive Committee on the allegations of "Project Paperless" seeking a licensing agreement from HDMA to compensate them for their alleged patent for office equipment configuration designed to scan and fax documents. Mr. Gray reported the Association was evaluating the comparative costs of defending a potential action versus settling for a modest fee.

# II. <u>FINANCIAL/GOVERNANCE MATTERS (Executive Committee Book, Tab A, Pages 11-21).</u>

#### A. 2011 Financial Results.

Ms. Ann Bittman (HDMA Executive Vice President and COO) presented the unaudited financial results for 2011. There was a net surplus of \$107,500 versus a projected surplus of \$50,600. The surplus was achieved due to higher sponsorship revenue and savings in almost every expense category. None of the funds in the SBDA reserve fund (\$180,000) were used. Operating revenue was slightly under projection due to small shortfalls in both distributor member dues and manufacturer member dues. Allied member dues increased as did conference and education seminar registration fees and sponsorship revenue. Operating expenses were \$13,000 below budget. Spending from the reserve fund was as budgeted — \$450,000 for the Role of the Distributor study and \$325,000 contribution to the Center for Healthcare Supply Chain Research. The reserve fund experienced a net loss on investments of \$288,000 versus budgeted net income of \$325,000. The balance as of December 31, 2011 was \$11.27 million, or at the target of one year's operating expenses.

The audit should be completed the week of February 27 2012. Thus far, no issues or irregularities have been identified.

#### B. 2012 Budget Update.

Six weeks into 2012, the Association is off to a good start. Distributor member dues are slightly lower than budgeted while manufacturer dues are significantly higher. Registration and sponsorships for program meetings are at or above expected levels.

III. 2012 ORGANIZATIONAL GOALS (Tab B, Pages 22-25). President Gray reported on long-term strategic goals, organizational and operational matters, advocacy, communications, and the Center for Healthcare Supply Chain Research. He noted significant progress in the communications area with the hiring of John Parker. A draft HDMA-Distributor communication piece was circulated. Some concern was expressed

about illustrating what the distributor does through a "medicine chest" graphic. Staff will make revisions.

#### IV. <u>DISCUSSION ISSUES (Executive Committee Book, Tab C)</u>.

#### A. Pedigree/Traceability (Executive Committee Book, Tab C, Page 26).

Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) and Liz Gallenagh, Esq. (HDMA Vice President, Government Affairs and General Counsel) (who participated by teleconference) provided an update on pedigree/traceability. HDMA, working with a supply chain coalition (the Pharmaceutical Distribution Security Alliance), is seeking to arrive at a consensus position to propose to Congress as it considers the PDUFA legislation. HDMA would obtain most of its priorities under a compromise being considered. HDMA objectives and timelines were identified. The proposed compromise does not go as far as California and would relieve the pharmacy of most responsibilities. The Alliance will vote on the draft consensus document the week of February 20, 2012. If no agreement is reached, HDMA is considering moving forward with its proposed language, including the HDMA elements of traceability. HDMA continues to consult with FDA on this issue.

#### B. DEA (Executive Committee Book, Tab C, Page 33).

Mr. Kelly reported that HDMA met with DEA staff in December 2011 in an effort to improve communications. DEA continues to expect distributors to do more to evaluate their customers and customers' customers. The agency also promised more inspections. Mr. Kelly and Mr. Frank briefly discussed DEA's actions against Cardinal and CVS and provided an update of the legal proceedings. A temporary restraining order has been issued in both cases. The next hearing in the *Cardinal* case will occur on February 29, 2012. HDMA has prepared talking points. In addition, Representative Mary Bono Mack (R-CA) invited HDMA to participate in a hearing on March 1 to address prescription drug diversion. John Gray will testify on behalf of HDMA.

Mr. Frank suggested that HDMA could file an *amicus curiae* brief in the *Cardinal* litigation. A discussion ensued as to the desirability of HDMA filing such a brief. There was general consensus that industry needs specific guidelines, and needs to know the "rules of the road" in order to effectively participate in the desirable effort of curtailing prescription drug abuse.

Action: On motion duly made and seconded, the Executive Committee asked that OFW Law prepare a draft *amicus curiae* brief focusing on the policy issues and to circulate said brief to the Executive Committee for consideration and, if appropriate, approval for submission to the federal district court.

#### C. AMP Rule (Executive Committee Book, Tab C, Page 37).

Mr. Kelly provided an update on the status of the Average Manufacturers Price (AMP) rule. On February 2, the Centers for Medicare and Medicaid Services

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(CMS) issued the proposed rule to implement changes in the AMP reporting process as mandated by the Affordable Care Act.; HDMA staff will work with the Reimbursement Task Force do develop and submit comments on the proposed rule. Comments are due to CMS on April 2.

#### D. Sunshine Act (Executive Committee Book, Tab C, Page 40).

Mr. Kelly provided an update on the proposed regulations implementing the Physician Payment Sunshine Act. HDMA will comment and express concerns about the definition of "applicable manufacturer" and "common ownership. Comments are due to CMS on February 17.

- V. <u>NEXUS AWARD</u>. Following discussion of nominees, the Executive Committee decided to award the 2012 Nexus Award to John Borschow (Borschow Hospital and Medical Supplies).
- VI. STRATEGIC PLANNING (Handout). Mr. William Hale (The Hale Companies) facilitated a strategic planning session. President Gray provided an introduction and a discussion of HDMA program and financial needs going forward. Mr. Perry Fri briefly reviewed the findings of the 2009 Booz & Company analysis, which showed HDMA requiring additional revenue in order to meet program needs, and discussed updated versions of these slides. He also reviewed future financial projections and highlighted measures HDMA has taken to cover the previously anticipated budget shortfalls thus far.

A number of potential future scenarios were discussed, including:

- 1. Mergers
- 2. Conferences
- 3. Dues increases/expand membership eligibility

Following discussion, it was decided:

To further explore potential mergers with HIDA and IFPW.

To explore the possibility of holding a DMC International and Expo

To consider expanding membership categories to include a category for distributors which primarily distribute med/surg products

To explore the formation of a Healthcare Supply Chain Council to speak with one voice on issues that impact the entire supply chain

The idea of pursuing other industry association mergers was rejected.

The notion of a super trade show was rejected. .

Consideration of changes in member dues structure was tabled for the time being.

Action: On motion duly made and seconded, the Executive Committee agreed to carry over the 2011 surplus into the 2012 operating budget and for this carryover of annual operating surplus to be standard operating procedure going forward.

There being no further business, the meeting was adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel

Dated: March 9, 2012

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Ann W. Bittman, HDMA Secretary

Dated: March // 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

**EXECUTIVE COMMITTEE CONFERENCE CALL** 

April 6, 2012 10:00 AM EDT

CONFIDENTIAL HDA\_MDL\_000156148

# Minutes of the HDMA Executive Committee Conference Call

April 6, 2012 10:00 AM EDT

#### **HDMA Executive Committee Members Present:**

David Moody (Chair) CEO, Mutual Wholesale Drug Company

David Neu (Vice Chairman) President, AmerisourceBergen Drug Corporation

Ken Couch President, Smith Drug Company
John M. Gray President and CEO, HDMA

Paul Julian Executive Vice President and Group President, McKesson Corp.

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

Ted Scherr President and CEO, Dakota Drug
Dale Smith Chairman and CEO, HD Smith

#### **HDMA and CHSCR Staff:**

Perry Fri Senior Vice President, Industry Relations, Membership

& Education

#### **Outside Legal Counsel:**

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC (OFW Law)

#### **PROCEEDINGS**

I. WELCOME AND INTRODUCTION. President John Gray thanked Executive Committee members for agreeing to participate in a conference call to address recent activity with respect to suspicious order monitoring and the role of healthcare distributors. HDMA has testified before Congress and prepared an amicus curiae brief for filing with the federal Court of Appeals in the Cardinal v. Holder litigation.

Chairman Moody and Vice Chairman Neu expressed concern about the trend of recent developments and thought it time for the Executive Committee to review recent events and plot a course for going forward.

President Gray reviewed recent activities and options for moving forward.

1. Partnership at Drugfree.org (formerly Partnership for a Drug-Free America) (PDFA). HDMA has been invited to participate in a program with the PDFA to study how government and industry can better manage the pharmaceutical supply chain to eliminate controlled substance diversion and abuse. PDFA has submitted

a proposal to HDMA for the first phase of the project. That proposal was shared with Executive Committee members on April 2, 2012.

Action: On motion duly made and seconded, \$200,000 was allocated from reserves to fund Phase I of the PDFA project.

- 2. HDMA is sponsoring the National Governors Association Prescription Drug Abuse Reduction Policy Academy. This is a special project that NGA is undertaking to address the growing incidence of prescription drug abuse in the United States. HDMA contributed \$25,000 to help underwrite this project.
- 3. HDMA is stepping up its efforts to educate the public, through the media, about the controlled substance supply chain and efforts being undertaken by distributors to prevent diversion and reduce prescription drug abuse.
- 4. President Gray reported that HDMA, along with outside counsel (OFW Law), plan to meet with Rich Cooper, Esq. and Bob Bennett, Esq. of Williams & Connolly to discuss other potential means of engaging DEA to better understand and manage suspicious ordering monitoring efforts.
- 5. HDMA is coordinating its efforts with NACDS.

There being no further, the conference call adjourned.

Prepared by:

Richard L. Frank, Counsel

Richard 2 France

Dated: May 8, 2012

Approved by:

Ann W. Bittman, HDMA Secretary

Dated: May 8, 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

#### **EXECUTIVE COMMITTEE MEETING**

JW Marriott San Antonio Hill Country San Antonio, Texas

June 10, 2012

CONFIDENTIAL HDA\_MDL\_000156151

# Minutes of the HDMA Executive Committee Meeting

#### JW Marriott San Antonio Hill Country San Antonio, Texas

#### June 10, 2012

#### **ATTENDANCE**:

#### **HDMA Executive Committee Members Present:**

David Moody (Chair) CEO, Mutual Wholesale Drug Company

David Neu (Vice Chair) Senior Vice President and President, AmerisourceBergen Drug

Corporation

Ken Couch President, Smith Drug Company John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

Ted Scherr President & CEO, Dakota Drug, Inc.

Dale Smith Chairman and CEO, HD Smith (via conference call)

#### **HDMA Executive Committee Members Absent:**

Paul Julian Executive Vice President & Group President, McKesson Corp.

#### **HDMA Staff Present:**

Ann Bittman HDMA Executive Vice President & COO
Anita Ducca HDMA Vice President, Regulatory Affairs

Perry Fri, Sr. HDMA Vice President, Industry Relations, Membership &

Education

Elizabeth Gallenagh HDMA Vice President, Government Affairs and General Counsel

(via conference call)

Patrick Kelly, Sr. HDMA Vice President, Government Affairs
Brooke Naylor HDMA Vice President, Meetings & Conferences

John Parker HDMA Vice President, Communications

Ted Pezzullo HDMA Vice President, Information Technology and Facilities

Karen Ribler Executive Vice President & COO, Center for Healthcare

Supply Chain Research

#### Legal Counsel

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

#### **PROCEEDINGS**

- I. <u>WELCOME AND INTRODUCTION</u>. President John Gray thanked Executive Committee members for participating in the Business & Leadership Conference. He noted an excellent attendance is expected for the conference and a productive agenda.
  - A. Chairman Dave Moody (Mutual Wholesale Drug Company) welcomed the Executive Committee and noted that the morning's focus would be on pedigree and DEA matters; the Board meeting in the afternoon will cover a broader range of topics.

# B. <u>Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 7-15).</u>

Richard L. Frank (OFW Law), HDMA Outside Counsel, drew the Executive Committee's attention to minutes of the February 16, 2012 Executive Committee meeting at Pebble Beach, California and the April 6, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the February 16, 2012 Executive Committee meeting were approved.

Action: On motion duly made and seconded, the minutes of the April 6, 2012 Executive Committee conference call were approved.

#### C. Antitrust Policy Review (Executive Committee Materials, Page 4).

Mr. Frank drew the Executive Committee's attention to the HDMA Antitrust Policy. He reminded the Executive Committee of HDMA's unqualified policy of strict compliance with the antitrust laws and noted that the agenda and background materials had been reviewed and approved in advance. Mr. Frank advised that meeting proceedings would be closely monitored and interrupted if and when topics or discussions created even the appearance of antitrust noncompliance.

#### D. Legal Issues Report.

Mr. Frank presented a short legal issues update.

- FDA Grand Jury in Puerto Rico Distributor Investigation no further activity since February 16, 2012 meeting. HDMA is still awaiting dates from OCI Investigator and Assistant U.S. Attorney for interview. HDMA is not a target of the investigation.
- <u>Qui Tam Litigation</u> Motions to Dismiss and a brief in opposition were filed in February 2012. Oral argument was held on May 18, 2012. The Judge's decision on the Motion to Dismiss could come at any time.

- Cardinal Health v. Holder (DEA) HDMA filed an amicus curiae brief in support of Cardinal Health's position before the Federal Court of Appeals for the District of Colombia Circuit. Cardinal subsequently reached a settlement with DEA and withdrew its appeal. The DEA administrative proceeding was terminated; Cardinal Health agreed to a two-year suspension of its Lakeland facility registration and some enhanced regulatory oversight by DEA.
- <u>Project Paperless</u> President Gray informed the Executive Committee that HDMA settled the case for \$32,500 and now has a license to continue its copy-scan-to-computer activities.

# II. <u>FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A)</u>.

#### A. Financial Update.

Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial update through April 30, 2012. Ms. Bittman reported the Association's financial condition is strong and that they are projecting operating results for 2012 at slightly better than budget. Projected year-end net surplus is slightly above \$280,000. If the carry-over surplus from 2011 of \$107,500 is included, the Association is projecting an operating surplus of \$389,000 for 2012. This figure assumes that the Business & Leadership Conference will meet its net income target. Currently, income is approximately \$112,000 shy of budget, meaning the projected year-end surplus could be correspondingly reduced.

On the revenue side, through April 30, 2012, collections are \$637,000 ahead of budgeted revenue due to higher manufacturer dues, increased sponsorship revenue, improved results from the Distribution Management Conference (DMC), utilization of the SBDA reserve fund (\$183,500), and new sponsorship revenue of \$26,000 from the HBW research project.

On the expense side, through April 30, 2012, expenses were \$356,000 over budget due, in large part, to the planned addition of the 4% discretionary 401(k) contribution, increased professional fees, and slightly higher expenses from the DMC.

As of April 30, 2012, the reserve fund balance is \$12.17 million, which meets the target of maintaining one year's operating expenses.

# B. <u>Center for Healthcare Supply Chain Research Board of Directors (Executive Committee Materials, Tab A, pages 28-30).</u>

Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research) presented the proposed slate of officers and Board members for the Center which requires approval by the HDMA Executive Committee.

Vice Chairman (completing Hal Korman's term that ends December 2012) – Jeff Watson, President, Apotex Corporation

Board Member – Robert Potter, Executive Vice President, Sales and Channel Development, Mylan Inc.

Board Member – Rebecca Lyons, Esq., Vice President, Strategy and Supply Chain Services, Johnson & Johnson Health Care Systems

Action: On motion duly made and seconded, the slate of officers and Board members was unanimously approved.

#### III. UPDATE ON STRATEGIC PLANNING PROCESS.

Mr. Perry Fri (HDMA Vice President, Industry Relations, Membership & Education) presented a brief update on the strategic planning process from the February 2012 meeting. The financial situation has improved providing more time to consider and implement structural changes. The ability to carry over surpluses into the next year's operating budget, as approved by the Executive Committee in February, has helped (\$107,500 from 2011). Outside Counsel has indicated that a By-Laws change is not required to include medical/surgical distributors as members. Mr. Fri has reached out to PSS and Owens & Minor to gauge their interest. Efforts continue to explore growth internationally both with membership and meetings. Mr. Gray is exploring opportunities with IFPW. The Executive Committee encouraged him to discuss the issue with Mark Parrish to see if some form of greater collaboration is possible. HDMA/HIDA dual members on the HDMA Executive Committee (McKesson, Cardinal) will let Mr. Gray know if there is support within their companies for pursuing greater collaboration between HDMA and HIDA, but the consensus was that it is not likely at this time. Finally, HDMA management will review the BLC registration fee structure and determine whether any revision to the fees is warranted for 2013.

#### IV. <u>DISCUSSION ISSUES (Executive Committee Materials, Tab C, pages 48-56).</u>

#### A. Pedigree.

Mr. Patrick Kelly (HDMA Vice President, Government Affairs) and Ms. Liz Gallenagh (HDMA Vice President, Government Affairs and General Counsel) provided an update on federal pedigree matters. Senators Bennet (D-CO) and Burr (R-NC) have offered the PDSA (healthcare industry consortium) amendment. Stakeholders, including House and Senate staff, FDA, the Pew Charitable Trust, PDSA, and others, are participating in the debate. Senate staff has set a goal of June 18, 2012 to address and resolve all concerns with the hope of including the amendment in the PDUFA extension legislation. The Bennet/Burr amendment includes a traceability model (not track and trace) by lot number. FDA continues to support traceability to the unit level. The California law begins to take effect in 2015 for manufacturers.

#### B. Prescription Drug Abuse, Diversion and DEA.

Executive Committee members expressed satisfaction with HDMA's role in supporting industry efforts to gain greater clarity from DEA as to what is needed to comply with suspicious order monitoring requirements. Mr. Mike Kaufmann (Pharmaceutical Segment, Cardinal Health, Inc.) thanked Executive Committee members and HDMA for its support during its litigation with DEA. Mr. Kaufmann summarized an NACDS initiative which would rely substantially on SureScripts to electronically capture all controlled substance prescriptions and orders. NACDS is considering support for legislation which would require that all such prescriptions and orders flow through SureScripts or something similar. Challenges include opposition from the American Medical Association and the 27 states which currently do not permit electronic prescriptions.

Mr. Kelly reported that controlled substance related matters that have played a prominent role in the PDUFA process include Senator Manchin's (D-WV) language to reschedule hydrocodone combination products from Schedule III to Schedule II. HDMA is opposing the amendment. HDMA is looking for carve-out language for wholesalers should the Manchin amendment pass. Additional Congressional activity includes Representative Bono Mack's (R-CA) letter to the Secretary of the US Department of Health and Human Services and the US Attorney General seeking clear guidance from DEA on prescription drug diversion issues. Senators Grassley (R-IA) and Whitehouse's (D-RI) requested GAO report on DEA policies and their potential impact on drug shortages. Finally, Senators Baucus (D-MT) and Grassley sent a letter to opioid manufacturers requesting information about financial contributions to entities supporting greater access to pain medicines.

President Gray reported that the \$200,000 previously approved by the Executive Committee to work with the Partnership for a Drug Free America likely will be applied instead to other DEA related activities and he will keep them posted.

There being no further, the conference call adjourned.

Prepared by:

Richard L. Frank, Counsel

Richard & Frank

Dated: June 21, 2012

Approved by:

Ann W. Bittman, HDMA Secretary

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Dated: June 21, 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

#### **EXECUTIVE COMMITTEE MEETING**

The Ritz Carlton Palm Beach Manalapan, Florida

**September 30, 2012** 

CONFIDENTIAL HDA\_MDL\_000156157

# Minutes of the HDMA Executive Committee Meeting

The Ritz Carlton Palm Beach Manalapan, Florida September 30, 2012

#### ATTENDANCE:

#### **HDMA Executive Committee Members Present:**

David Moody (Chair) CEO, Mutual Wholesale Drug Company (via conference call)

David Neu (Vice Chair) President, AmerisourceBergen Drug

Corporation

Ken Couch President, Smith Drug Company John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

Ted Scherr President & CEO, Dakota Drug, Inc.
Dale Smith Chairman and CEO, HD Smith

#### **HDMA Executive Committee Members Absent:**

Paul Julian Executive Vice President & Group President, McKesson Corp.

#### **HDMA Staff Present:**

Ann Bittman HDMA Executive Vice President & COO
Anita Ducca HDMA Vice President, Regulatory Affairs

Perry Fri HDMA Senior Vice President, Industry Relations,

Membership & Education

Elizabeth Gallenagh HDMA Vice President, Government Affairs and General Counsel

Patrick Kelly

HDMA Senior Vice President, Government Affairs
Brooke Naylor

HDMA Vice President, Meetings & Conferences

John Parker HDMA Vice President, Communications

Ted Pezzullo HDMA Vice President, Information Technology and Facilities Karen Ribler Executive Vice President & COO, Center for Healthcare

Supply Chain Research

#### Legal Counsel Present:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

**Guest Present:** 

George Koch, Esq. K&L Gates

#### **PROCEEDINGS**

- I. <u>WELCOME AND INTRODUCTION</u>. President John Gray thanked Executive Committee members for attending the Annual Board and Membership Meeting. He noted an excellent attendance is expected for the conference and a productive agenda.
  - A. Chairman Dave Moody (Mutual Wholesale Drug Company) welcomed the Executive Committee by conference call and sent his regrets that for medical reasons he would be unable to attend in person. He thanked Vice Chairman David Neu (AmerisourceBergen Drug Corp.) for chairing the meeting. Vice Chairman Neu thanked the Executive Committee for their attendance and participation.

#### B. Antitrust Policy Review (Executive Committee Materials, Page 4).

Richard L. Frank (OFW Law), HDMA Outside Counsel, drew the Executive Committee's attention to the HDMA Antitrust Policy. He reminded the Executive Committee of HDMA's unqualified policy of strict compliance with the antitrust laws and noted that the agenda and background materials had been reviewed and approved in advance. Mr. Frank advised that meeting proceedings would be closely monitored and interrupted if and when topics or discussions created even the appearance of antitrust noncompliance.

# C. <u>Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 6-11).</u>

Mr. Frank drew the Executive Committee's attention to minutes of the June 10, 2012 Executive Committee meeting at the J.W. Marriott San Antonio Hill Country Hotel in San Antonio, Texas.

Action: On motion duly made and seconded, the minutes of the June 10, 2012 Executive Committee meeting were approved.

#### D. Legal Issues Report.

Mr. Frank presented the legal issues update.

- 1. West Virginia Lawsuit (June 2012) West Virginia Attorney General Darrell McGraw filed suit against 14 out-of-state drug distributors alleging violations of the State Controlled Substances Act and Consumer Credit and Protection Act for their roles in allegedly supplying controlled substances to state "pill mills." AG McGraw seeks to enjoin the distributors from distributing any controlled substances for non-medical purposes, recover damages, establish medical monitoring for drug abuse victims, and mandate reporting suspicious orders to state authorities.
- 2. DEA Actions in Florida

- (a) CVS Caremark on February 4, 2012, the DEA served an immediate suspension order (ISO) on two CVS pharmacies in Sanford, Florida alleging that the pharmacies were distributing controlled substances in violation of federal law. The matter went before the DEA Administrative Law Judge who issued a recommendation on June 8, 2012 to revoke the pharmacies' DEA registrations. On August 31, 2012, DEA Administrator Michelle M. Leonhart accepted the ALJ's recommendations and issued the final Order to revoke both registrations. CVS may choose to challenge the revocations before the U.S. Court of Appeals for the District of Columbia Circuit.
- (b) Walgreens on September 14, 2012, DEA announced that it had issued an ISO to a Walgreens distribution facility in Jupiter, Florida.
- (c) Arizona suit against McKesson the State of Arizona sued McKesson in Arizona state court alleging violations of the State Consumer Fraud Law. The State alleges that McKesson provided false and misleading average wholesale prices to First DataBank and Medi-Span thereby causing false and inflated prices for the retail sale of certain drugs.
- 3. Qui Tam Litigation (Streck) on July 3, 2012, the District Court dismissed all counts against the "service fee" defendants and most of the counts against the "discount" defendants. The Court did permit the case to proceed against the "discount" defendants for conduct from January 1, 2007 to October 28, 2008, the date Streck filed the Complaint. Streck has moved to amend the judgment dismissing the "service fee" defendants; that motion is still pending.
- 4. Grand Jury Subpoena in Puerto Rico Distributor Investigation no change in status.

# II. <u>FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A)</u>.

#### A. Nomination of 2013 Board Officers.

Action: On motion duly made and seconded, the Executive Committee unanimously nominated the following slate of officers for a one-year term (Executive Committee Materials, Tab A, page 13). This slate will be submitted to the full membership on October 1, 2012.

- David Neu, President, AmerisourceBergen Drug Company for a one-year term as HDMA Chairman
- 2. Ted Scherr, President and CEO, Dakota Drug, for a one-year term as HDMA Vice Chairman

#### B. August 2012 Financial Statements.

- 1. Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial update through August 2012 (Executive Committee Materials, Tab A, pages 14-23). Financial reports include the Balance Sheet, Operating Income Statement, Reserve Fund Income Statement, and Consolidated Income Statement. As of August 31, 2012, the Reserve Fund exceeded \$12 million. This exceeds HDMA's target of maintaining one year's operating expenses and reserves. Operating revenue was \$11.49 million and operating expenses were \$7.84 million for a current net surplus of \$3.65 million. The projected net surplus for year-end is \$350,000 which consists of the current projected net surplus of \$242,000 plus the carry-over of \$108,000 from the 2011 operating surplus. Overall dues revenue is \$262,000 higher than budgeted due to new members and higher manufacturer sales revenue. Projected expenses include the discretionary 401(k) contribution for employees of 4%.
- Proposed 2013 Budget (Executive Committee Materials, Pages 24-38) –
  Ms. Bittman presented the proposed 2013 budget including the Operating
  Budget and Reserve Fund budget. The Operating Budget reflects a deficit of
  \$285,000 which would be more than covered by the projected 2012 operating
  carryover surplus of \$350,000.

Discussion ensued. Several Executive Committee members expressed the view that a budget balanced without use of the prior year's operating surplus would be preferable. Staff was tasked to prioritize activities and present a balanced budget for Executive Committee consideration by mid-November 2012. In addition, it was agreed that a sponsor should be obtained for the June Board of Directors dinner.

Center Board of Directors (Executive Committee Materials, Pages 39-40) –
Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare
Supply Chain Research (Center)) presented the proposed slate of officers and
directors for the Center.

Action: On motion duly made and seconded, The Executive Committee approved the Nominating Committee's slate of officers and directors for the Center.

# III. <u>STRATEGIC PLANNING PROCESS – UPDATE (Executive Committee Materials, Tab B).</u>

President John Gray and Mr. Perry Fri (HDMA Senior Vice President, Industry Relations, Membership & Education) presented a brief update of action items from the strategic planning process:

- Discussions continue with IFPW and its President, Mark Parrish, to conduct joint activities and possible integration of meetings and conferences.
- No real interest has been expressed in pursuing a merger with HIDA but there is still the possibility of developing a separate HDMA dues category for medical-

- surgical distributors. That allows them to pay based on their pharmaceutical sales rather than total company sales.
- A modest decrease in BLC registration fees for small manufacturers is under consideration.
- Exploration of a broadening of the membership categories to include selfdistributing chains was discussed briefly and put on hold.
- John Gray explained that Express Scripts is still exploring options for a new organization. It was agreed that HDMA should remain involved in these discussions.

#### IV. <u>DISCUSSION ISSUES (Executive Committee Materials, Tab C).</u>

#### A. Rx Drug Abuse and Diversion.

Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) updated the Executive Committee. A Controlled Substance Abuse Task Force has been empaneled which is looking at federal, state and public relations issues. The GPPC and RAC recommend focusing first on public relations issues.

Mr. John Parker (HDMA Vice President, Communications) presented an update on the current state of play regarding how wholesalers are being portrayed in the media and their implications for HDMA members. The GPPC has recommended a strategy of education, advocacy and collaboration. The goal is to find a public relations firm to help execute the strategy. Proposals from APCO and GMMB will be made to the Board on October 1, 2012. Discussion ensued regarding the scope of a PR program and the possibility of handling some of this work with staff and member assets. No decisions or recommendations were made. PR firm proposals will be considered by the full Board and the Executive Committee and staff will put together a plan including HDMA staff, member, and third-party assets.

There being no further business, the meeting adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel

Richard 2 Franc

Dated: October 22, 2012

Ann W. Bittman, HDMA Secretary

Dated: October 22, 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

#### **EXECUTIVE COMMITTEE CONFERENCE CALL**

November 16, 2012 1:00 PM EST

CONFIDENTIAL HDA\_MDL\_000156163

### Minutes of the HDMA Executive Committee Conference Call

#### November 16, 2012 1:00 PM EST

#### **HDMA Executive Committee Members Present:**

David Neu (Chair) President, AmerisourceBergen Drug Corporation

Ted Scherr (Vice Chair)

Ken Couch

John M. Gray

President and CEO, Dakota Drug

President, Smith Drug Company

President and CEO, HDMA

Paul Julian Executive Vice President and Group President, McKesson Corp.

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

David Moody CEO, Mutual Wholesale Drug Company

#### **HDMA Executive Committee Members Absent:**

Dale Smith Chairman and CEO, HD Smith

#### **HDMA Staff:**

Ann Bittman HDMA Executive Vice President & COO Anita Ducca HDMA Vice President, Regulatory Affairs

Perry Fri HDMA Sr. Vice President, Industry Relations, Membership &

Education

Elizabeth Gallenagh HDMA Vice President, Government Affairs and General Counsel

Patrick Kelly

HDMA Senior Vice President, Government Affairs
Brooke Naylor

HDMA Vice President, Meetings & Conferences
HDMA Vice President, Communications

Ted Pezzullo HDMA Vice President, Information Technology and Facilities Karen Ribler Executive Vice President & COO, Center for Healthcare Supply

Chain Research

#### **Outside Legal Counsel:**

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC (OFW Law)

#### Guest:

George Koch, Esq. K&L Gates

#### **PROCEEDINGS**

I. <u>WELCOME AND INTRODUCTION</u>. President John Gray welcomed the Executive Committee members to the conference call and noted that two main agenda items, finalization of the 2013 budget and consideration/approval of a communications initiative

regarding wholesalers' role in fighting prescription drug abuse would be the main topics during the half-hour call.

- II. <u>ANTITRUST POLICY REVIEW</u>. Richard L. Frank (OFW Law), HDMA Outside Counsel, reminded the Executive Committee of HDMA unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no problems. Mr. Frank will monitor the conversation and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.
- III. <u>ELECTION/POLITICAL UPDATE</u>. Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) provided a short briefing of election results and matters which may be addressed during the "lame duck" session of Congress. Potential issues include possible pedigree legislation with Congressional staff seeking comments from all interested participants. HDMA has submitted comments urging uniform standards, raising concerns regarding lot number based pedigree for all transactions, and urging that any licensing requirements not disrupt successful state requirements. Possible tax code revisions could be part of Congress's efforts to avoid the "fiscal cliff" with HDMA remaining wary of LIFO repeal and possible savings by reducing payments to pharmacies and providers under Part B.

President Gray drew the Executive Board's attention to the November 16, 2012 edition of the *Wall Street Journal*, which had a story about DEA bringing actions against FedEx and UPS with respect to controlled substances. He noted that DEA's efforts have broadened the initiative and created potential allies for HDMA and its members.

IV. COMMUNICATIONS INITIATIVE ON PRESCRIPTION DRUG ABUSE AND DIVERSION (Phase I Proposal Circulated with Executive Committee Materials). Mr. John Parker (HDMA Vice President, Communications) briefly discussed the elements of Phase I of APCO's proposed strategic communications effort to address prescription drug abuse and diversion with a focus on the contributions made by distributors. APCO proposed qualitative and quantitative research designed to arm HDMA with the appropriate resources to identify threats, mitigate risks, educate primary stakeholders and build the foundation for a leadership platform. The research phase would last approximately three months with findings to be shared with the Executive Committee at its next meeting on February 22, 2013. The proposed budget is \$250,000.

Discussion ensued. Executive Committee members asked that APCO's efforts be coordinated closely with efforts from communications firms currently being utilized by individual members. Mr. Mike Kaufman (Cardinal Health, Inc.) suggested the RAND initiative also be considered and noted that individual members may want to fund that program. President Gray will recirculate the RAND proposal for discussion.

Action: On motion duly made and seconded, Phase I of the APCO communications effort to address prescription drug abuse and diversion was approved with a maximum budget of \$250,000 to be taken out of reserves.

V. 2013 BUDGET (Three (3) Budget Options were Circulated with the Executive Committee Materials). President Gray introduced the topic by noting the Executive Committee had asked staff to review and revise the proposed budget for 2013 which had been discussed at the September 30, 2012 meeting. Executive Committee members had raised questions as to whether the surplus from 2011 and anticipated surplus from 2012 should be included in the 2013 budget or invested in reserves. Staff has been asked to prepare a draft budget which did not include 2011 and 2012 surpluses.

Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the three options, all of which included no dues increases. The three options included updated assumptions with regard to revenues and expenses.

Discussion of all three options ensued. Option 2 included an additional \$155,000 of expense reductions which HDMA senior management did not believe would have a significant impact on operations or priorities. Option 2 resulted in an anticipated operating deficit of \$74,600. It included HDMA not renewing its membership in the U.S. Chamber of Commerce and the National Association of Wholesalers. The only concern expressed about pulling out of the NAW, was what impact, if any, it would have on individual member dues to NAW. President Gray said he would investigate that issue.

Action: On motion duly made and seconded, the Executive Board adopted budget Option 2, with a portion of the carryover surplus from 2011/2012 being used to eliminate the \$74,600 anticipated operating deficit for 2013, thereby producing a balanced budget. The remaining surpluses from 2011/2012 would be invested in reserves. The timeline of discussing HDMA's draft budget during the October meeting but finalizing that budget on a conference call with the Executive Committee with more current financial data in November will be used in the future.

There being no further, the conference call adjourned.

Prepared by:

Richard L. Frank, Counsel

Richard 2 Franc

Dated: November 29, 2012

Approved by:

Ann W. Bittman, HDMA Secretary

ann W. B. Hulan

Dated: November 30, 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

### **EXECUTIVE COMMITTEE CONFERENCE CALL**

December 14, 2012

CONFIDENTIAL HDA\_MDL\_000156167

### Minutes of the HDMA Executive Committee Conference Call

#### December 14, 2012

#### **ATTENDANCE**:

#### **HDMA Executive Committee Members Present:**

David Neu (Vice Chair) President, AmerisourceBergen Drug

Corporation

David Moody (Chair) CEO, Mutual Wholesale Drug Company

Ken Couch President, Smith Drug Company
John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

Paul Julian Executive Vice President & Group President, McKesson Corp.

Ted Scherr President & CEO, Dakota Drug, Inc.
Dale Smith Chairman and CEO, HD Smith

**HDMA Staff Present:** 

Perry Fri Senior Vice President, Industry Relations, Membership and

Education

Patrick Kelly Senior Vice President, Government Affairs

Legal Counsel Present:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

#### **PROCEEDINGS**

- I. <u>WELCOME AND INTRODUCTION</u>. President John Gray welcomed the Executive Committee to the conference call and thanked everyone for their time and interest. The two principal topics include:
  - (1) Interest in and need for HDMA participation in established or ad hoc organizations designed to expand and deepen the voice of pharmacy stakeholders in public policy debates; and
  - (2) Potential expansion of HDMA membership to include PBMs such as Express Scripts.

Background materials were circulated to all Executive Committee members prior to the conference call.

President Gray reported that there are several new initiatives aimed at expanding and deepening the voice of the pharmacy industry in public policy debates. The Health

Leadership Council convened a meeting of stakeholders to consider development of a communications program in 2013 to address and engage federal policy and legislative issues likely to come up dealing with pharmacy. Participants included the AMA, PhRMA, BIO, AdvaMed, NACDS, and HDMA. The goal would be for the umbrella group to work with the communications assets of the individual associations to coordinate and enlarge message development and dissemination.

Discussion ensued. Executive Committee members generally view the initiative positively, but concluded that HDMA would need to make decisions on an issue-by-issue basis. Some HDMA members already participate in the Health Leadership Council and will continue to do so. It was agreed that HDMA would cooperate where there is a common point of view. It was also decided that there would be no need to replicate the efforts of the Health Leadership Council.

The notion of potential expanded HDMA membership categories to include pharmacy benefit managers such as Express Script emanated from a desire by some PBMs to find a vehicle (such as HDMA) to better communicate their views and concerns about public policy issues. One potential idea would be the establishment of an Rx Leadership Forum to engage policy issues from a communications and government affairs perspective.

Discussion ensued. Executive Committee members generally believe there were many points of disagreement between distributors and PBMs which would make a single association representing both sets of views difficult. There was also concern expressed regarding duplicating the efforts of the Health Leadership Council.

There being no further business, the meeting adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel

Richard 2 Franc

Dated: January 3, 2013

Ann W. Bittman, HDMA Secretary

Dated: January 3, 2013

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

#### **EXECUTIVE COMMITTEE MEETING**

The Four Seasons Hotel Washington, D.C.

February 22, 2013

CONFIDENTIAL HDA\_MDL\_000156170

# Minutes of the HDMA Executive Committee Meeting

The Four Seasons Hotel Washington, D.C.

February 22, 2013

#### **ATTENDANCE:**

#### **HDMA Executive Committee Members Present:**

David Neu (Chair) President, AmerisourceBergen Drug Corporation

Ken Couch President, Smith Drug Company John Gray President & CEO, HDMA

David Moody CEO, Mutual Wholesale Drug Company

Dale Smith Chairman and CEO, HD Smith

#### **HDMA Executive Committee Members Absent:**

Paul Julian Executive Vice President & Group President, McKesson Corp.

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

Ted Scherr (Vice Chair) President & CEO, Dakota Drug, Inc.

#### **HDMA Staff Present:**

Ann Bittman HDMA Executive Vice President & COO
Anita Ducca HDMA Vice President, Regulatory Affairs

Perry Fri HDMA Senior Vice President, Industry Relations, Membership &

Education

Elizabeth Gallenagh HDMA Vice President, Government Affairs and General Counsel

Patrick Kelly HDMA Senior Vice President, Government Affairs Brooke Naylor HDMA Vice President, Meetings & Conferences

John Parker HDMA Vice President, Communications

Ted Pezzullo HDMA Vice President, Information Technology and Facilities
Karen Ribler Executive Vice President & COO, Center for Healthcare

Supply Chain Research

#### Legal Counsel:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

#### **Guests:**

George W. Koch, Esq. Counsel

Michael Tuffin Managing Director, Washington, DC, APCO Worldwide Priscilla VanderVeer Director, Corporate Communications & Issues Management,

2

APCO Worldwide

Chrystine Zacherau

Director, Health Care Research, APCO Insight, APCO Worldwide

#### **PROCEEDINGS**

I. <u>WELCOME AND INTRODUCTION</u>. President John Gray thanked the Executive Committee members for attending the meeting and he briefly reviewed the agenda.

#### A. Chairman's Remarks.

Chairman Dave Neu (AmerisourceBergen Drug Corporation) welcomed the Executive Committee and extended the apologies of Paul Julian, Mike Kaufmann, and Ted Scherr, who were unable to attend. Chairman Neu thanked Dave Moody (Mutual Wholesale Drug Company) for his leadership as Chairman and his many years of service to the Association. He also briefed the Executive Committee on the day he spent with staff getting to know them and their areas of responsibility better. He assured the Executive Committee that the staff is performing at a high level and the Association is in capable hands.

#### B. Antitrust Policy Review (Executive Committee Materials, Page 3).

Richard L. Frank (OFW Law), HDMA outside counsel, reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no problems. Mr. Frank will monitor the conversation and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

# C. <u>Approval of Prior Meetings Minutes (Executive Committee Materials, Pages 4-16).</u>

Mr. Frank drew the Executive Committee's attention to the minutes of the September 30, 2012 Executive Committee meeting in Manalapan, Florida.

Action: On motion duly made and seconded, the minutes of the September 30, 2012 Executive Committee meeting were approved.

Mr. Frank drew the Executive Committee's attention to the minutes of the November 16, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the November 16, 2012 Executive Committee conference call were approved.

Mr. Frank drew the Executive Committee's attention to minutes of the December 14, 2012 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the December 14, 2012 conference call were approved.

#### D. Legal Issues Report.

Mr. Frank presented the legal issues update.

- Qui Tam Litigation There is no new activity in connection with this lawsuit.
  Plaintiff Streck has moved for entry of final judgment to the court's July 3,
  2012 Order which dismissed the service fee defendants entirely from the case.
  The service fee defendants raised no objections to entering a final Order. If
  the court grants Plaintiff's motion, the dismissal of the service fee defendants
  in the case becomes appealable and this part of the case could move to
  briefing before the Third Circuit U.S. Court of Appeals.
- 2. Grant Jury Subpoena in Puerto Rico Distributor Investigation On December 7, 2012, a federal grand jury returned a 61-count indictment against 23 individuals and three corporations for various offenses involving the wholesale distribution of prescription drugs. The indictment alleged criminal drug diversion by Martin Thuna and associates through various companies, including Drogueria de la Villa. Drogueria is a subsidiary of HDMA member FMC Distributors. HDMA has previously provided documents to the government in connection with this investigation. Mr. Frank noted that it is unlikely the government will be interested in HDMA for further documents or as a fact witness. It is also unlikely that the defense would subpoena testimony or documents from HDMA.

In response to a question regarding membership of FMC, Mr. Frank noted that the By-Laws provide that a criminal <u>conviction</u> of any member may subject that member to expulsion by the Executive Committee of the Board of Directors. However, the By-Laws do not provide the same type of action for an indictment.

- 3. State of West Virginia Lawsuit Former West Virginia Attorney General Darrell McGraw sued 14 out-of-state drug distributors alleging violations of the state Controlled Substances Act and Consumer Credit and Protection Act for their roles in allegedly supplying controlled substances to state "pill mills." With Mr. McGraw's recent defeat in the election of Republican opponent Patrick Morrisey, it is unclear whether or on what schedule these lawsuits will proceed. Mr. Moody reported that recently district attorneys in counties in West Virginia have brought or threatened similar lawsuits on a local basis. Staff was asked to gather additional information about these actions and circulate it to members.
- 4. <u>DEA Actions in Florida</u> the CVS Caremark matter appears to be resolved. At the end of November 2012, DEA instituted registration revocation proceedings against three Walgreen retail stores in Florida but did not immediately suspend their registrations. These matters are still pending.

- 5. Arizona's Suit Against McKesson The state sued McKesson alleging violation of the state consumer fraud law. The state alleges that McKesson provided false and misleading average wholesale price information to First Databank and Medi-Span, thereby causing false and inflated prices for the retail sale of certain drugs. This case is pending.
- II. <u>FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A, Pages 18-32)</u>. Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the 2012 year-end unaudited financial statements and an update on the 2013 budget.

#### A. 2012 Unaudited Financial Results.

Ms. Bittman reported that HDMA ended 2012 with an unaudited operating net surplus of \$282,000 versus a projected net surplus of \$242,000 and an original budgeted net surplus of zero. The surplus was the result of higher manufacturer dues revenue, increased exhibit fees at DMC, additional sponsors at the ABMM, and moving the SBDA reserve fund into other income to cover law firm work on specialty matters.

Overall, operating revenue was \$11.85 million, slightly under projection and significantly ahead of the original budget. Operating expenses were \$11.57 million, slightly under the latest projection and 2% over the Original Budget.

The reserve fund experienced an excellent gain of \$1.358 million, or 12% in 2012 due, in large part, to the performance of the overall market. Reserve fund expenditures included \$62,000 for Phase 1 of the APCO public relations project with another \$187,500 for that project to be spent during the first quarter of 2013. The reserve fund balance sits at \$11.935 million as of year-end.

HDMA's auditors Tate & Tyron are finishing their work and will submit a draft audit report by the end of February. To date, they have noted no problems or proposed adjustments to the financial statements.

#### B. 2013 Budget Update.

Slightly less than two months into the new year, dues collections are ahead of schedule. However, manufacturer dues are projected to be under budget for the year due to consolidation and resignations. Ninety-seven percent of pledged sponsorship revenue has already been received. Sponsorships for DMC and BLC are over initial budgeted projections.

#### C. Organizational Goals (Executive Committee Materials, Pages 29-32).

President Gray briefly reviewed the Association's organizational goals for 2013.

- III. MEMBERSHIP REPORT (Tab B, Pages 33-36). Mr. Perry Fri (HDMA Senior Vice President, Industry Relations, Membership & Education) presented the Membership Report. There is one new Distributor member with three members resigned or not renewed. Total number of Distributor members sits at 33. Associate members are down from 155 to 142. Allied members have increased from 50 to 54.
- IV. PUBLIC RELATIONS RESEARCH REPORT (Tab C, Page 37 Handout). Mr. John Parker (HDMA Vice President, Communications) provided a brief background on Phase 1 of the public relations project and the selection of APCO to be the public relations partner. Mr. Michael Tuffin (Managing Director, Washington, DC, APCO Worldwide) introduced the work to date, which involved mostly research of opinion leaders and views of thought leaders about the problem of controlled substance diversion and abuse and the roles played by doctors, clinics, distributors, manufacturers and government. APCO conducted a series of focus groups and interviews, looking at who opinion leaders blame for drug abuse and diversion and possible solutions. Quantitative research will focus on what messages and platforms may be effective to publicize the extensive efforts made by distributors to address the problem. APCO recommended that HDMA be a primary resource in getting the story out and helping respond to crises.

Phase 2, scheduled from March to December 2013, will involve an educational program, developing messages for crisis and rapid response, creating communications tools for this program, educating target stakeholders and speaking at relevant events.

Action: On motion duly made and seconded, the Executive Committee approved Phase 2 with a \$265,000 budget to be taken out of reserves. Chairman Neu reiterated his interest in having the APCO project continue in coordination with work being done by Rand.

#### V. <u>DISCUSSION ISSUES (Executive Committee Materials, Tab D)</u>.

#### A. Pedigree/Traceability (Page 41).

Liz Gallenagh, Esq. (HDMA Vice President, Government Affairs and General Counsel) provided an update on recent federal activity regarding pedigree and traceability. Working draft bills are currently circulating in the House (Representatives Latta, Matheson, and Upton) and the Senate (Senators Burr, Bennet, Alexander, and Harkin). HDMA is part of a supply chain coalition working hard to find a compromise solution to require and implement pedigree and traceability with federal preemption. Other key players include FDA and Pew. With the California requirements becoming effective in 2015, manufacturers are anxious to see a federal solution. The coalition is targeting the summer of 2013 to consider a bill or the industry focus may shift to California. Mr. Gallenagh discussed the key issues being debated by the various parties.

#### B. Sunshine Act Final Rule (Page 44).

Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) briefed the Executive Committee on the newly released final Sunshine Act rules which explicitly apply the reporting requirements to distributors. In an action which appeared inconsistent with the Sunshine Act statute and the regulatory proposal, CMS's final rule requires that if the distributor holds title to the goods, they are covered by the rule and must make annual transparency reports of certain marketing expenses. The Reimbursement Task Force is considering the rule and seeking to ascertain its exact impact on HDMA members. HDMA plans to meet with CMS and to visit interested leaders on Capitol Hill. If these initial actions do not bear fruit, a lawsuit may be considered.

#### C. ASP and Sequestration (Page 50).

On March 1, 2013, the ASP reimbursement for Part B Medicare will revert to ASP plus 4%. This will be caused in part by sequestration. HDMA is attempting to maintain the exemption for prompt pay discount.

#### D. Regulatory Affairs (Page 51).

Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) provided an update on regulatory matters, including postponement for seven additional years of the DOT tote marking requirement; further engagement with DEA, including Al Santos (Deputy to Joe Rannazzisi) who will speak at the DMC and the possibility of a face-to-face meeting with DEA. USP has agreed to not move forward with its comprehensive GDP/security guidance. There is significant new activity on hydrocodone combination products with several Congressional and DEA efforts to have them rescheduled from Schedule 3 to Schedule 2. A ruling from FDA regarding the proprietary of such a rescheduling is expected soon.

Disposal of DEA products is also becoming a growing challenge for distributors. HDMA has filed a comment and is urging the establishment of an interagency task force.

- VI. <u>UPDATED DASHBOARD (Executive Committee Materials, Tab E, Page 67)</u>. Mr. Patrick Kelly reviewed the current issues dashboard, noting only one significant change with disposal/take-back issues being elevated from a B to an A.
- VII. CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH. Ms. Karen Ribler (Executive Vice President & COO, Center for Healthcare Supply Chain Research) presented the Center report. Two vacancies exist on the Center Board. The following nominations were submitted:
  - Peyton R. Howell, MHA (replaces Tony Pera). Ms. Howell is Senior Vice President of AmerisourceBergen Corporation and President, Global Sourcing and Manufacturer Relationships.
  - 2. Kirk Kaminsky (replaces Mike Walchirk). Mr. Kaminsky is Vice President, Strategy and Business Development, McKesson Corporation.

Action: On motion duly made and seconded, the slate of nominees to fill seats on the Center Board were approved.

A discussion ensued regarding nominations for the 2013 Nexus Award. The committee members agreed with a proposal from Mr. Gray that, going forward, nominations for the Nexus Award be solicited from only the HDMA Board, the Center Board and past Nexus Award winners who are still in the industry. Further nominations will be solicited in this manner and the Executive Committee will convene by telephone conference over the next month or two to select the winner.

- VIII. MEETINGS, CONFERENCES, AND EDUCATIONAL PROGRAMS (Executive Committee Materials, Tab G). No discussion.
- IX. <u>EXECUTIVE SESSION</u>. (Separate confidential minutes.)

There being no further business, the conference call adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel

Richard 2 Frank

Dated: March 20, 2012

Ann W. Bittman, HDMA Secretary

Dated: March 20, 2012

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

## **EXECUTIVE COMMITTEE MEETING**

J.W. Marriott Orlando, Grande Lakes Orlando, FL

June 2, 2013

CONFIDENTIAL HDA\_MDL\_000156178

## Minutes of the HDMA Executive Committee Meeting

#### J.W. Marriott Orlando, Grande Lakes Orlando, FL

June 2, 2013

#### **ATTENDEES**

#### **HDMA Executive Committee Members Present:**

David Neu (Chair) Senior Vice President and President, AmerisourceBergen Drug

Corporation

Ted Scherr (Vice Chair)

Ken Couch

John Gray

President & CEO, Dakota Drug, Inc.

President, Smith Drug Company

President & CEO, HDMA

Paul Julian (by telephone) Executive Vice President & Group President, McKesson Corp.

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

David Moody CEO, Mutual Wholesale Drug Company

Dale Smith Chairman and CEO, HD Smith

#### HDMA and Center for Healthcare Supply Chain Research (HSCR) Staff Present:

Ann Bittman HDMA Executive Vice President & COO
Anita Ducca HDMA Vice President, Regulatory Affairs

Perry Fri HDMA Senior Vice President, Industry Relations, Membership &

Education

Elizabeth Gallenagh HDMA Vice President, Government Affairs and General Counsel

Patrick Kelly HDMA Senior Vice President, Government Affairs Brooke Naylor HDMA Vice President, Meetings & Conferences

John Parker HDMA Vice President, Communications

Ted Pezzullo HDMA Vice President, Information Technology and Facilities

Karen Ribler Executive Vice President & COO, CHSCR

Legal Counsel:

Arthur Tsien, Esq. Olsson Frank Weeda Terman Matz PC

Guest:

George Koch, Esq.

#### **PROCEEDINGS**

I. <u>WELCOME AND ADMINISTRATIVE MATTERS</u>. Chairman Dave Neu (AmerisourceBergen Drug Company) called the meeting to order at 11:05 am and welcomed all attendees.

#### A. Antitrust Policy Review (Executive Committee Materials, Page 4).

Arthur Tsien (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no problems. He stated that he will monitor the conversation and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

#### B. Approval of Prior Meeting Minutes (Executive Committee Materials, Page 6).

John Gray (HDMA President and CEO) drew the Executive Committee's attention to the minutes of the February 22, 2013 Executive Committee meeting in Washington, D.C.

Action: On motion duly made and seconded, the minutes of the February 22, 2013 Executive Committee meeting were approved.

### C. Legal Issues Update.

Mr. Tsien presented the legal issues update.

- HHS Medical Privacy Regulations In the preamble to its final medical privacy regulations issued in January 2013, HHS adopted several very restrictive interpretations that effectively hinder "refill reminder" letters, sponsored by pharmaceutical companies, that retail pharmacies send their patients without patient authorization (affirmative patient opt-in). This issue is potentially of interest to the extent that distributor members offer network and other services to their retail pharmacy customers.
- 2. Walsh v. AmerisourceBergen Corp. In December 2011, plaintiff Walsh, a former AmerisourceBergen internal auditor, filed a federal qui tam whistleblower case against AmerisourceBergen in Pennsylvania. In late 2012, the United States declined to intervene. In February 2013, the complaint was unsealed. The suit alleges that AmerisourceBergen offered free pill-counting machines and other discounts to independent pharmacies to induce them into entering into vendor relationships with AmerisourceBergen, in violation of the False Claims Act. The case is pending.

#### 3. DEA Matters

- a. <u>DEA Settlement with UPS</u>. In March 2013, DEA entered into a Non-Prosecution Agreement with UPS in which UPS agreed to forfeit \$40 million in payments it had received from allegedly unlawful online pharmacies. UPS also agreed to implement a compliance program designed to ensure that unlawful online pharmacies will not be able to use UPS's services to distribute drugs.
- b. <u>Walgreens v. DEA</u>. As previously summarized, DEA had issued an immediate suspension order to a Walgreens distribution facility in Florida in 2012, and Walgreens sought judicial review of the order. The case was argued before the U.S. Court of Appeals for the D.C. Circuit in March 2013, so a decision may be imminent.
- c. <u>DEA Settlement with CVS</u>. In April 2013, CVS agreed to pay \$11 million in civil penalties to settle allegations regarding recordkeeping violations.
- 4. <u>Previously Reported Matters</u> There were no significant developments involving other previously reported matters.

#### II. <u>DISCUSSION ISSUES</u>

#### A. Pedigree/Traceability Legislation (Executive Committee Materials, Page 44).

Following an introduction by Mr. Gray, Liz Gallenagh (HDMA Vice President, Government Affairs and General Counsel) provided an update on federal pedigree and traceability legislation. Among other differences, requirements in the House bill would require FDA rulemaking for "Phase 2" unit level traceability to become effective, while in the Senate bill "Phase 2" would be self-effectuating. In addition, in the Senate bill, federal requirements for licensure would be a "floor," with no "ceiling" on more stringent state requirements. Under the House bill, federal requirements would be both a "floor" and a "ceiling" on state licensure requirements. Extensive discussion followed, including HDMA's concerns with the Pharmaceutical Distribution Security Alliance (PDSA).

Action: On motion duly made and seconded, the Executive Committee recommended to the HDMA Board that: (1) HDMA continue to support federal legislation that would establish federal pedigree requirements that preempt state requirements, and (ii) HDMA continue to participate in PDSA.

Mr. Gray commended Ms. Gallenagh for her efforts on pedigree legislation.

#### B. Sunshine Rule (Executive Committee Materials, Page 53).

Patrick Kelly (HDMA Senior Vice President, Government Affairs) discussed CMS's final Sunshine Rule and HDMA's efforts to get distributors excluded from the scope of the final rule. CMS is said to be working on a "Subregulatory Guidance" that would clarify that the final rule does not apply to full service distributors. An HDMA Task Force draft letter to OMB requests, in the alternative, a 36 month extension of the Sunshine Rule's compliance date if a Guidance to address HDMA's concerns cannot be adopted. Following extensive discussion, there was general agreement that the letter to CMS should not ask for a 36 month extension.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board direct that the comment to OMB not ask for a 36 month extension of the compliance date of the Sunshine Rule.

#### C. ASP and Sequestration (Executive Committee Materials, Page 55).

Mr. Kelly reported that HDMA is seeking to have the planned 2% sequestration cut in reimbursement for services and drugs limited to services, and not be applied to Part B drugs. During discussion, there was general agreement that this effort needs to proceed, even if it is unlikely to succeed.

#### D. <u>Pfizer Direct-To-Consumer Sales (Executive Committee Materials, Page 57).</u>

There was brief discussion regarding Pfizer's announced plans to sell prescription drugs directly to consumers. Pfizer's intent appears to be to offer an alternative to questionable Internet pharmacy sales, not to bypass distributors and retail pharmacies.

## III. <u>UPDATE ON PUBLIC RELATIONS PROJECTS (Executive Committee Materials, Page).</u>

#### A. APCO (Executive Committee Materials, Page 24).

John Parker (HDMA Vice President, Communications) gave a brief overview of his planned presentation to the Board regarding the ongoing APCO project on improving public relations with regard to prescription drug diversion.

# B. <u>Senator Boxer's Draft Legislation (Commission To Study Prescription Drug Abuse).</u>

Mr. Kelly discussed Senator Barbara Boxer's (D-CA) draft legislation that would establish a commission with industry and government representatives to study prescription drug abuse and issue a non-binding report. Discussion followed.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board direct HDMA to support the commission concept, and to work with Senator Boxer's staff to ensure that the commission's report does not devolve into an enforcement-based recommendation to Congress.

#### C. RAND Study Proposal (Executive Committee Materials, Page 37).

Mr. Gray discussed a proposal from RAND to undertake a study entitled "Improving Prescription Drug Regulation Policy." If approved, an initial presentation regarding the project will be presented in September.

Action: On motion duly made and seconded, the Executive Committee authorized spending \$500,000 from HDMA's reserve fund to fund the study.

There being no further business, on motion duly made and seconded, the meeting was adjourned at 12:40 pm.

Prepared by:

Arthur Y. Tsien, Counsel Dated: June 26, 2013

Approved by:

Ann W. Bittman, HDMA Secretary

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Dated: June 26, 2013

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

## **EXECUTIVE COMMITTEE MEETING**

The Greenbrier White Sulphur Springs, West Virginia

**September 29, 2013** 

CONFIDENTIAL HDA\_MDL\_000156184

# Minutes of the HDMA Executive Committee Meeting

# The Greenbrier White Sulphur Springs, West Virginia

#### September 29, 2013

#### **ATTENDEES**

#### **HDMA Executive Committee Members Present:**

Dave Neu (Chair) Sr. Vice President and President, AmerisourceBergen Drug Corp.

Ted Scherr (Vice Chair) President & CEO, Dakota Drug, Inc.

Ken Couch President, Smith Drug Company, Div. J.M. Smith Company

John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

David Moody CEO, Mutual Wholesale Drug Company

Dale Smith Chairman and CEO, HD Smith

Mark Walchirk President, U.S. Pharmaceutical, McKesson Corporation

### HDMA and Center for Healthcare Supply Chain Research (CHSCR) Staff Present:

Ann Bittman Executive Vice President & COO

Perry Fri Sr. Vice President, Industry Relations, Membership & Education

The following staff were present only for Section III of the meeting:

Anita Ducca

Vice President, Regulatory Affairs

Anita Ducca Vice President, Regulatory Affairs

Elizabeth Gallenagh Vice President, Government Affairs and General Counsel

Patrick Kelly Senior Vice President, Government Affairs Brooke Naylor Vice President, Meetings & Conferences

John Parker Vice President, Communications

Ted Pezzullo Vice President, Information Technology and Facilities

Karen Ribler Executive Vice President & COO, CHSCR

#### Legal Counsel:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

Guest:

George Koch, Esq., Counsel

#### **PROCEEDINGS**

I. WELCOME AND ADMINISTRATIVE MATTERS. Chairman Dave Neu (AmerisourceBergen Drug Corp.) called the meeting to order at 3:00 pm and welcomed all attendees to the Annual Board and Membership Meeting (ABMM). He recognized Mark Walchirk (U.S. Pharmaceutical, McKesson Corporation), who is replacing Paul Julian on the Executive Committee. Chairman Neu briefly reviewed the agenda for the Executive Committee meeting and the ABMM event.

President John Gray welcomed the Executive Committee, staff and guests to the meeting and reported that HDMA's 10-year effort to see the adoption of national pedigree (track and trace) legislation was close to being realized. The U.S. House of Representatives has approved the legislation and the Senate is poised to vote as soon as the budget/debt ceiling issues are resolved. Mr. Gray congratulated his team for a wonderful effort of advancing this legislation on a competitive bipartisan bicameral basis.

- A. Antitrust Policy Review (Executive Committee Materials, Page 4). Counsel Richard L. Frank (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.
- B. Approval of Prior Meeting Minutes (Executive Committee Materials, Page 6).

  Mr. John Gray (HDMA President and CEO) drew the Executive Committee's attention to the minutes of the June 2, 2013 Executive Committee meeting in Orlando, Florida.

Action: On motion duly made and seconded, the minutes of the June 2, 2013 Executive Committee meeting were approved.

- C. <u>Legal Issues Update</u>. Mr. Frank presented the legal issues update.
  - 1. HHS Medical Privacy Regulations On September 19, 2013, HHS issued Guidance designed to address concerns with regard to the regulation of sponsored refill reminder communications. The Guidance clarifies that covered entities (pharmacies) can use business associates to carry out these plans. The business associate can be compensated at "fair market value." The covered entity can be compensated by the sponsor for a "reasonable amount" which is defined as "direct and indirect costs related to the refill reminder or medication program, including labor, materials, and supplies as well as capital and overhead costs." Mr. Frank also noted that a lawsuit had been filed in federal District Court challenging the new HHS privacy regulation on First Amendment grounds. Adheris, Inc. v. Kathleen Sebelius, et al., No. 1:13-cv-01342 (D.D.C. filed Sept. 5, 2013).

Following discussion, Mr. Frank was asked to circulate a memorandum to Association members summarizing the current status of the sponsored refill reminder regulation and Guidance.

- 2. <u>U.S. et al., ex rel. Streck v. Allergan, Inc., et al., Civ. No. 08-5133 (E.D. Pa).</u>

  The Judge in the "whistleblower" lawsuit rejected plaintiff's motion to enter a final order dismissing the service fee defendants. The case will move forward as to the remaining discount defendants with no appeal allowable until final judgment is issued on both classes of defendants.
- 3. Preemption of State and Local Stewardship and Disposal Laws OFW Law issued an informal opinion concluding that DEA's proposed disposal and takeback rule will not effectively preempt state and local disposal and stewardship laws. The Controlled Substances Act CSA currently has a fairly well-accepted anti-preemption "savings" provision.
- 4. <u>Drug Enforcement Administration (DEA) Matters and Litigation</u> There were no new significant developments involving DEA investigations or litigation.

#### II. FINANCIAL/GOVERNANCE MATTERS (Executive Committee Materials, Tab A).

A. <u>Nominating Committee</u> – President Gray requested that the Executive Committee nominate Mr. Dave Neu (Chairman) and Mr. Ted Scherr (Dakota Drug, Inc.) to serve second terms.

Action: On motion duly made and seconded, the Executive Committee unanimously approved the nomination of Mr. Dave Neu for Chairman and Mr. Ted Scherr for Vice Chairman. These nominations will be forwarded to the Full Membership for consideration and approval.

B. <u>Financial Matters</u> – Ms. Ann Bittman (HDMA Executive Vice President and COO) presented the financial/budget report. Ms. Bittman drew the Executive Committee's attention to the 2013 year-to-date financial reports and the proposed 2014 budget.

Total operating revenue through August 31 is \$11.55 million and total operating expenses are \$7.62 million for a current net surplus of \$3.93 million. The projected net deficit at year-end is \$32,000 as compared to a budgeted projected net deficit of \$74,000. Revenue decreases were in the areas of the Business and Leadership Conference, sponsorship, and interest income. Spending decreases were in the areas of the Business and Leadership Conference, travel/entertainment, depreciation, and marketing. With the anticipated passage of the HDMA supported pedigree (track and trace) legislation, the Track and Trace Seminar should exceed budget expectations and possibly lead to a year-end surplus.

The reserve fund stands at \$12.58 million, which more than meets HDMA's target of maintaining one year's operating expenses (\$11.71 million).

Ms. Bittman previewed the proposed budget which reflects a deficit of \$659,000. Proposed revenue of \$12.43 million is \$754,000 (6.5%) higher than 2013 projected revenue due in large part to revenue of \$730,000 from the first ever Distribution Management Conference International. Anticipated expenses for that event are \$698,000 resulting in a projected \$32,000 net income.

The proposed budget calls for a reduction in dues revenue for both distributors and manufacturers. This is due in large part to acquisitions and consolidation. Operating expenses for 2014 are projected to increase \$1.38 million (11.8%) due to the addition of the DMCI and \$427,000 in payroll and benefit expense increases.

Discussion ensued. Chairman Neu noted that the Executive Committee needs to figure out how to fund critical services. He noted that with salaries and benefits rising at normal rates, and dues and sponsorships flat to negative, the Association faces a challenge of aligning its programs, priorities and resources. President Gray reported that the staff is very stable and highly experienced.

Staff was asked to develop options for increasing revenue (expanded membership, increased dues or sponsorships) and for reducing costs. Options will be circulated over the next month with a conference call scheduled in November to review and finalize the budget for 2014.

Staff was also asked to lay out the benefits and risks of potential HDMA international activities.

<u>Lease Extension</u> – The Association has been approached by its landlord and given the opportunity to extend the current lease at a fair market rate, with additional incentives including several months of free rent and a buildout allowance for office refurbishment,. Assuming that HDMA staff and the landlord reach agreement on terms, HDMA will proceed with signing a lease amendment extending the lease term through December of 2025.

## III. <u>DISCUSSION ISSUES (Executive Committee Materials, Tab B)</u>.

A. Pedigree (Track and Trace) -Ms. Liz Gallenagh (HDMA Vice President, Government Affairs and General Counsel) reported that the Association's 10-year effort to enact national pedigree legislation was nearing realization with the House of Representatives' passage of the Drug Quality and Security Act (H.R. 3204). The bill is scheduled to go before the full Senate as soon as that body completes action on the budget/debt ceiling issues. The majority of HDMA's priorities are realized in the legislation, which calls for national uniformity and full implementation over a 10-year period. FDA will be called upon to facilitate implementation via public meetings, guidance documents and/or regulations

Chairman Neu, Executive Committee members and President Gray congratulated Ms. Gallenagh for her tireless effort to achieve the Association's number one legislative priority.

There being no further business, on motion duly made and seconded, the meeting was adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel Dated: October 21, 2013

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Ann W. Bittman, HDMA Secretary

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Dated: October 22, 2013

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

### **EXECUTIVE COMMITTEE CONFERENCE CALL**

November 26, 2013 2:00PM EST

CONFIDENTIAL HDA\_MDL\_000156190

## Minutes of the HDMA Executive Committee Conference Call

#### November 26, 2013 2:00-3:00 PM EST

#### **ATTENDEES**

#### **HDMA Executive Committee Members Present:**

Dave Neu (Chair) Sr. Vice President and President, AmerisourceBergen Drug Corp.

Ted Scherr (Vice Chair) President & CEO, Dakota Drug, Inc.

Ken Couch President, Smith Drug Company, Div. J.M. Smith Company

John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

David Moody CEO, Mutual Wholesale Drug Company

Dale Smith Chairman and CEO, HD Smith

Mark Walchirk President, U.S. Pharmaceutical, McKesson Corporation

#### **HDMA Staff Present:**

Ann Bittman Executive Vice President & COO

Perry Fri Sr. Vice President, Industry Relations, Membership & Education

Patrick Kelly Senior Vice President, Government Affairs

#### Legal Counsel:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

#### Guest:

George Koch, Esq., Counsel

#### **PROCEEDINGS**

- I. <u>WELCOME AND INTRODUCTION</u>. President John Gray welcomed the Executive Committee to the conference call and noted that the main agenda item is finalization of the 2014 budget. The committee will also discuss plans for HDMA's international activities, the 2014 Nexus Award, and how to address budget issues hence.
- II. ANTITRUST POLICY REVIEW. Counsel Richard L. Frank (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary

and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.

#### III. 2013 BUDGET.

Ms. Ann Bittman (HDMA Executive Vice President & COO) reported that the association expects to end the year better than budgeted, with a Projected Operating Surplus of \$70,688 as compared to a Budgeted Operating Deficit of \$74,664. The Reserve Fund stands at \$12.56 million at October 31<sup>st</sup>.

Mr. Gray asked the Committee to consider funding employees' 401(k) accounts with a 4% discretionary contribution, which has been made in past years, but was not budgeted in 2013, due to financial constraints. Discussion ensued.

Action: On motion duly made and seconded, the Executive Committee agreed to fund a 4% 401(k) plan contribution (approximately \$173,000) for calendar year 2013. The 2013 operating surplus is to be used to fund this contribution, with any additional funds needed to come out of the Reserve Fund.

#### IV. 2014 BUDGET.

Ms. Bittman reviewed the HDMA draft 2014 Operating Budget. She highlighted changes from the budget discussed at the Executive Committee meeting on September 29. The latest draft reduced the projected deficit from \$659,525 to \$451,925. She also presented several areas for potential additional cost savings for the Committee's consideration in order to further reduce the projected budget deficit.

Mr. Gray discussed the progress on planning the first International Pharmaceutical Distribution Conference to be held in Beijing in October 2014. He noted that the conference is budgeted to realize a loss of almost \$97,000 because staff have lowered the planned registration fee from the earlier budget draft, and that this loss is an investment in a longer term international strategy that is expected to result in significant additional revenue in the future.

Discussion ensued.

Action: On motion duly made and seconded, the Executive Committee agreed that the 2014 Operating Budget should result in a deficit of \$96,924\* after making the following changes to the draft presented:

- 1) Add additional educational seminar revenue of \$32,763
- 2) Add \$30,000 in spending to join the Alliance to Prevent the Abuse of Medicines
- 3) Move the Capital Budget spending, and related \$112,000 in Depreciation expense,

from the Operating Budget to the Reserve Fund budget

- \* 4) Cover any loss from the 2014 Beijing conference (budgeted to be \$96,924) out of the Reserve Fund.
  - 5) Find the remaining \$240,238 in budget cuts needed through a combination of reducing political consultant and state lobbyist spending and implementing up to 50% of the staffing changes identified for the Committee.

The Committee considered changing the existing policy that an amount equal to 100% of annual operating expenses be maintained in the Reserve Fund to a policy requiring a lower target level, such as, requiring 1) a minimum of 50% of Operating Expenses be maintained in the Reserve Fund and 2) allowing 2% of any amount above that 50% floor be used annually to subsidize the Operating Budget, in addition to any separately approved Reserve Fund spending. A proposal for this policy change will be made at the February Executive Committee meeting.

#### V. 2014 NEXUS AWARD

Mr. Gray proposed that Paul Julian, Executive Vice President and Group President, McKesson Corporation, be chosen as the recipient of the 2014 Nexus Award.

Action: The committee voted to award the 2014 Nexus Award to Mr. Paul Julian. They also agreed that Mr. Julian would be notified in advance that he is the award recipient.

There being no further business, on motion duly made and seconded, the meeting was adjourned.

Prepared by:

Richard 2 Franc

Richard L. Frank, Counsel Dated December 10, 2013 Approved by:

Ann W. Bittman, HDMA Secretary

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Dated: December 6, 2013

# HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

## **EXECUTIVE COMMITTEE MEETING**

The Ritz-Carlton, Tysons Corner McLean, VA

February 27, 2014

CONFIDENTIAL HDA\_MDL\_000156194

# Minutes of the HDMA Executive Committee Meeting

# The Ritz-Carlton, Tysons Corner McLean, VA

#### February 27, 2014

#### **ATTENDEES**

#### **HDMA Executive Committee Members Present:**

Dave Neu (Chair) Sr. Vice President and President, AmerisourceBergen Drug Corp. Ken Couch President, Smith Drug Company, Div. J.M. Smith Company

John Gray President & CEO, HDMA

Mike Kaufmann CEO, Pharmaceutical Segment, Cardinal Health, Inc.

David Moody CEO, Mutual Wholesale Drug Company

Dale Smith Chairman and CEO, HD Smith

Mark Walchirk President, U.S. Pharmaceutical, McKesson Corporation

#### **HDMA Executive Committee Members Absent:**

Ted Scherr (Vice Chair) President & CEO, Dakota Drug, Inc.

### HDMA and Center for Healthcare Supply Chain Research (CHSCR) Staff Present:

Ann Bittman Executive Vice President & COO
Anita Ducca Vice President, Regulatory Affairs

Perry Fri Executive Vice President, Industry Relations, Membership

& Education

John Howells Vice President, Industry Relations

Patrick Kelly Executive Vice President, Government Affairs

John Parker Sr. Vice President, Communications

Karen Ribler Executive Vice President & COO, CHSCR

#### Legal Counsel:

Richard L. Frank, Esq. Olsson Frank Weeda Terman Matz PC

#### **PROCEEDINGS**

I. <u>WELCOME AND ADMINISTRATIVE MATTERS</u>. Chairman Dave Neu (AmerisourceBergen Drug Corp.) called the meeting to order at 8:00 am and welcomed all attendees to the Executive Committee Meeting. He previewed the agenda, highlighting Drug Enforcement Administration (DEA) matters, pedigree/traceability implementation and the budget.

President John Gray welcomed the Executive Committee and staff to the meeting and introduced John Howells, who had recently been promoted to the position of Vice President for Industry Relations.

- A. Antitrust Policy Review (Executive Committee Materials, Page 5). Counsel Richard L. Frank (OFW Law, HDMA outside counsel) reminded the Executive Committee of HDMA's unqualified policy of strict compliance with both federal and state antitrust laws. He noted that the agenda and background materials had been reviewed in advance and raised no competitive concerns. He stated that he will monitor the meeting and, if necessary and appropriate, interrupt proceedings if topics or conversations raised concerns regarding antitrust compliance.
- B. Approval of Prior Meeting Minutes (Executive Committee Materials, Pages 6-15). Mr. Frank drew the Executive Committee's attention to the minutes of the September 29, 2013 Executive Committee meeting in White Sulphur Springs, West Virginia (The Greenbrier).

Action: On motion duly made and seconded, the minutes of the September 29, 2013 Executive Committee meeting were approved.

Mr. Frank also drew the Executive Committee's attention to the minutes of the November 26, 2013 Executive Committee conference call.

Action: On motion duly made and seconded, the minutes of the November 26, 2013 Executive Committee conference call were approved.

- C. <u>Legal Issues Update Executive Committee Materials, pages 16-19</u>). Mr. Frank presented the legal issues update.
  - 1. HHS Medical Privacy Regulations Guidance (Handout) On September 19, 2013, HHS issued Guidance entitled "The HIPAA Privacy Rule and Refill Reminders and Other Communications About a Drug or Biologic Currently Being Prescribed For the Individual" ("Guidance") in which it resolved outstanding issues regarding the scope of the refill reminder exemption from authorization, the meaning of "reasonable compensation" (now defined to include direct and indirect costs), and the compensation of business associates under the regulation. As a consequence of the Guidance, the vast majority of pharmacies have re-engaged these types of compliance/persistence programs.
  - Implementation of the Drug Supply Chain Security Act ("DSCSA") –
    Government Affairs staff are working on a variety of rulemaking initiatives to
    implement the DSCSA. Outside counsel are assisting with pertinent regulatory
    and legal issues, including the scope of the Act's preemption provisions with
    regard to state licensing laws.

3. <u>U.S., et al., ex rel. Streck v. Allergan, Inc., et al., Civ. No. 08-5133 (E.D. Pa)</u> — In November 2013, one of the four remaining discount defendants, Cephalon, served a third-party subpoena for documents upon HDMA. Subsequently, Cephalon and another discount defendant informed the court that they have reached an agreement to settle with the Relator. They asked for and obtained from the court a Stay of Discovery in order to pursue the state and federal government entities' approval of the settlement. HDMA has produced no documents and is awaiting further action from potential non-settling defendants not subject to the Stay.

Several members requested additional information regarding the status of the case and publicly available information regarding settlement terms. Mr. Frank will report back to the Committee.

4. Hydrocodone Rescheduling – DEA has issued a proposal to "up-schedule" hydrocodone combination drug products from Schedule III to Schedule II. Mr. Patrick Kelly (HDMA Executive Vice President, Government Affairs and Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) provided a brief update on HDMA engagement of the just-issued DEA proposal.

#### II. <u>DISCUSSION ISSUES (Executive Committee Materials, Tab A, pages 20-34.</u>

A. Drug Abuse and Diversion – H.R. 4069, sponsored by Representatives Marino (R-PA) and Blackburn (R-TN), has been introduced. It is entitled "Ensuring Patient Access and Effective Drug Enforcement Act of 2014." The legislation is designed to clarify existing authorities under the Controlled Substances Act by requiring greater transparency of the enforcement process and developing a forum to bring supply chain stakeholders, law enforcement, patient groups, providers, and regulators together to identify solutions to prescription drug abuse. HDMA is seeking additional sponsors, including interested Democrats in the House and Senate. The legislation addresses distributors' concerns with the lack of clarity in DEA's current enforcement scheme and would put in place the option of a corrective action plan prior to suspension. Such a process is currently available under the Federal Food, Drug, and Cosmetic Act.

Several members highlighted the importance of the legislation and directed staff to identify and engage additional resources to assist.

Action: On motion duly made and seconded, the Executive Committee allocated up to \$250,000 to be taken from reserves to hire a lobbyist to support H.R. 4069.

It was agreed that, for the next several months, all Executive Committee members will be invited to join the regular monthly Chair and Vice Chair calls with John Gray in order to discuss progress on the drug abuse and diversion issues, particularly H.R. 4069.

Mr. Kelly discussed other federal legislation currently pending as well as actions at the state level where bills to regulate pseudoephedrine and controlled substances as well as distributor/pharmacy thresholds are all pending.

The Drug Diversion/DEA Strategy Task Force met on December 11, 2013 and recommended the following actions:

- Partner with other supply chain shareholder groups (including the Alliance to Prevent the Abuse of Medicines, the National Community Pharmacists Association, the National Association of Drug Diversion Investigators, the National Association of Boards of Pharmacy and the National Governors Association).
- 2. Develop specific policy recommendations, including potential solutions to the enforcement issues identified by HDMA (see pages Executive Committee Materials, Tab A, 29-32).
- 3. Engage in initial HDMA public relations branding.

Several members suggested HDMA continue requesting face-to-face meetings with DEA every quarter and to document those requests and responses. Staff will prepare a brief questionnaire for members to identify requests they have made over the past five years, along with responses. Individual company information will be kept confidential by outside counsel.

- B. Pedigree/Traceability Implementation (Executive Committee Materials, Tab A, pages 35-38) Mr. Kelly reported that HDMA has organized implementation teams by subject matter and issue. The Traceability Implementation Work Group has had three in-person meetings and weekly calls since November 2013. HDMA continues to coordinate with PDSA, NACDS and FDA. Mr. Kelly identified key issues and the FDA implementation timeline. The matter of the scope of preemption under the DSCSA has been addressed by outside counsel.
- III. DASHBOARD REVIEW (Executive Committee Materials, Tab B, pages 53-55). Mr. Perry Fri (HDMA Executive Vice President, Industry Relations, Membership & Education) drew the Executive Committee's attention to the HDMA Issues/Initiatives Dashboard for the first quarter of 2014. A brief discussion ensued regarding minor changes to the Dashboard. The Dashboard will be submitted to the full Board for review and discussion at its meeting in June 2014.
- IV. CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH ("CHSCR")

  (Executive Committee Materials, Tab C, pages 56-60). Ms. Karen Ribler (CHSCR Executive Vice President & COO) updated the Executive Committee on CHSCR activities. Research projects for 2014 include:
  - 1. Understanding the benefits/risks of the global supply chain; and
  - 2. Biosimilar pharmaceuticals in Europe: Best Practices for the US Market

CHSCR is working collaboratively with the American Association of Colleges of Pharmacy ("AACP"), providing 75 AACP members access to the *Understanding Distribution* program. CHSCR will provide four workshops at the DMC. The CEO

Roundtable, featuring George Paz, Chairman and Chief Executive Officer, Express Scripts, Inc., is scheduled for April 1, 2014, in New York City.

Ms. Ribler reported that the CHSCR Board has nominated Albert Paonessa III (President, ANDA) to a Board position.

Action: On motion duly made and seconded, the Executive Committee unanimously approved Mr. Albert Paonessa III to serve on the CHSCR Board.

It was suggested that, prior to the June Board meeting, HDMA conduct a review of who is on HDMA's committees and the Center's Board of Directors and confirm that members are represented as they would like to be on these groups.

- V. <u>MEETINGS</u>, <u>CONFERENCES AND EDUCATION PROGRAMS</u> (Executive Committee Materials, Tab D, pages 61-73). Mr. Fri briefly updated the Executive Committee on upcoming meetings, including the Distribution Management Conference, Business and Leadership Conference, Annual Board and Membership Meeting, educational programs and the International Pharmaceutical Distribution Conference ("IPDC").
- VI. <u>FINANCIAL REPORT (Executive Committee Materials, Tab F, pages 90-108)</u>. Ms. Ann Bittman (HDMA Executive Vice President & COO) presented the financial report.
  - A. 2013 Unaudited Financial Statements. HDMA ended 2013 with an unaudited operating net surplus of \$17,000 versus the original budgeted net deficit of \$74,600. The surplus included an Executive Committee-authorized 4% discretionary contribution (\$172,600) to employee 401(k) accounts. Operating revenue came in at \$11,746,988, slightly lower than the original budget. Manufacturer member dues were down 5.7% but sponsorship was higher by 4%. Expenses were \$11,729,567, or slightly below the original budget. Payroll and rent were slightly higher than projected, and legal fees and meeting expenses were lower.

The reserve fund had an excellent net gain on investments of \$1,363,790, or 11.43% versus budgeted income of \$275,000. Spending out of reserves included \$457,764 for work on Phase I and Phase II of the APCO public relations project and HDMA's contribution to the Center for \$217,000.

The audit should be completed by the end of February, and the Audit Committee will meet via conference call in early April.

Mr. Fri reported that 88% of dues for 2014 have already been collected. HDMA has lost six Associate members and picked up four new ones.

- B. 2014 Organizational Goals (Executive Committee Materials, Tab F, Pages 100-104). Mr. Gray drew the Executive Committee's attention to the organizational goals set forth and urged members to call or E-mail with their thoughts and suggestions.
- C. <u>Budget Planning 2015-2020 (Handout)</u>. Ms. Bittman circulated the HDMA budget review 2015-2020, which contains relevant financial information (revenue and expenses) for the next six years. Chairman Neu said that the Executive Committee needs to engage budgetary issues to avoid the annual exercise of dealing with revenue shortfalls attributable to industry consolidation along with the need to cut spending on important programs to meet budget goals. He suggested the empanelling of three budget subcommittees to meet telephonically to discuss options for moving forward. The subcommittees include:
  - 1. Domestic revenue and business development (Dave Moody (Mutual Wholesale Drug Company), Ted Scherr (Dakota Drug, Inc.) and Dave Neu;
  - 2. Expenses Mike Kaufmann (Pharmaceutical Segment, Cardinal Health, Inc.) and Dale Smith (HD Smith); and
  - 3. International Revenue and business development Ken Couch Smith Drug Company, Div. J.M. Smith Company) and Mark Walchirk (U.S. Pharmaceutical, McKesson Corporation).

The three subcommittees will report their findings and recommendations at the June 2014 Executive Committee and Board meetings for further discussion.

There being no further business, on motion duly made and seconded, the meeting was adjourned.

Prepared by:

Approved by:

Richard L. Frank, Counsel

Richard & Frank

Dated: March 26, 2014

Ann W. Bittman, HDMA Secretary

aun w. Bittman

Dated: March 26, 2014